# **EXHIBIT A**



#### UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO:

County of Suffolk v. Abbott Laboratories, et al. Civ. Action No. 1:03-cv-10643 MDL NO. 1456 CIVIL ACTION NO. 01-12257-PBS

#### MEMORANDUM AND ORDER

October 26, 2004

Saris, U.S.D.J.

#### I. INTRODUCTION

Twenty-two pharmaceutical-manufacturer Defendants have filed individual memoranda in support of their motion to dismiss Suffolk County's Amended Complaint. The cross-cutting issues were addressed in In re Pharm. Indus. Average Wholesale Price Litig., \_ F. Supp. 2d \_ (D. Mass. Sept. 30, 2004). As all federal claims have been dismissed, this Order addresses the company-specific issues with respect to the remaining state law claims. The surviving claims include the allegations that (1) Defendants fraudulently misstate their average wholesale prices ("AWP's") in violation of New York Social Services Law Section 145-b (Count V); (2) Defendants violate the New York consumer protection law, N.Y. Gen. Bus. Law § 349, with respect to both



AWP and Best Prices schemes (Count VII); and (3) Defendants were unjustly enriched by the AWP and Best Prices schemes (Count IX).

#### II. DISCUSSION

#### A. Standard

Defendants move to dismiss the AWP and Best Prices claims under Federal Rule of Civil Procedure 9(b). Count V asserts a claim under New York Social Services Law Section 145-b, which applies to "false statement[s]," "deliberate concealment[s]," or "other fraudulent scheme[s] or device[s]." Rule 9(b) applies to this claim. See United States v. Karvelas, 360 F.3d 220, 227-28 (1st Cir. 2004) (holding that Rule 9(b) applies to False Claims Act because liability depends on presentation of a false or fraudulent claim and a mental state of at least reckless disregard of the truth).

Count VII pleads a violation of New York General Business

Law Section 349. While most courts have held that Rule 9(b) does

not apply to all claims under this statute, most courts have also
held that it is appropriate to require "specificity" in pleading
a violation of Section 349. See, e.g., Pelman v. McDonald's

Corp., 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003); Lava Trading

Inc. v. Hartford Fire Ins. Co., 326 F. Supp. 2d 434, 438

(S.D.N.Y. 2004); Petitt v. Celebrity Cruises, Inc., 153 F. Supp.

 $<sup>^{\</sup>rm 1}$  Other remaining Counts are for implied causes of action under New York Medicaid statutes and regulations (Counts III and IV).



2d 240, 264-65 (S.D.N.Y. 2001); see generally Gaidon v. Guardian Life Ins. Co. of Am., 94 N.Y.2d 330, 343 (N.Y. 1999) (holding Section 349 claims are "critically different" from fraud claims, for Section 349 is directed to protecting the consuming public). But cf. Volunteer Firemen's Ins. Servs., Inc. v. McNeil & Co., Inc., 221 F.R.D. 388, 393-94 (W.D.N.Y. 2004) (applying Rule 9(b) to false advertising and Section 349 claims where the complaint described a fraudulent scheme, without deciding whether Rule 9(b) applies in all cases). While an intermediate pleading standard may no longer be viable, see Swierkiewicz v. Sorema, N.A., 534 U.S. 506, 513-14 (2002), "the complaint should at least set forth minimal facts as to who did what to whom, when, where, and why although why, when why means the actor's state of mind, can be averred generally, " Educadores Puertorriqueños en Acción v. Hernandez, 367 F.3d 61, 68 (1st Cir. 2004). Also, barebones assertions will not suffice even under Rule 8(a).

Rule 9(b) does not apply to the remaining claims, unjust enrichment and implied causes of action, since these do not require a pleading of fraud or mistake.

#### B. AWP Claims

The Court dismisses Suffolk's AWP claims under Section 145-b and Section 349 against defendants Novartis, Purdue, and Ivax because there are no factual allegations regarding a spread, internal documents or government investigations from which an inference of fraud can reasonably be made.



For the remaining Defendants, Suffolk has alleged both the published AWP for a drug and what Suffolk believes is an accurate estimate of the actual average wholesale price of that drug. Suffolk explains that this information is based on "Suffolk's own investigations of pricing data." (Am. Compl. at ¶ 122.)

The so-called "Suffolk 13" companies complain vigorously that they should not be dragged into this multi-district litigation morass. They insist that the allegations concerning the spread are not particular enough because Suffolk has not disclosed the basis for its calculation and there are no other allegations (e.g., government investigations or the company's own internal documents) to support a claim of fraudulent pricing. See Karvelas, 360 F.3d at 231 n.11. I will defer ruling on the motions to dismiss of the Suffolk 13 and those other Defendants for whom Suffolk has not alleged specific facts beyond a spread. In complying with the automatic disclosure requirements, Suffolk shall disclose within three weeks all documents upon which it relied in calculating the spreads, and provide, in writing, a more definite statement of its method of calculation pursuant to Federal Rule of Civil Procedure 12(e). If there is a good faith basis for calculating a spread, the Court will deny the motion to dismiss. Any challenge to the method of calculation shall be made within fourteen days of this disclosure. In the interim, all discovery shall be stayed with respect to the Suffolk 13 and Defendants Amgen, Inc., Chiron Corporation, Fujisawa



Pharmaceutical Company, Ltd., Johnson & Johnson, Warrick Pharmaceuticals, and Wyeth.

#### C. <u>Best Price Claims</u>

Suffolk has asserted state-law claims concerning allegedly fraudulent Best Prices that Defendant manufacturers reported to the states. Defendants argue that these claims should be dismissed for failure to comply with Rules 8(a) and 9(b). With respect to most companies, Suffolk has not tied the Best Prices claims to any particular drugs, discounts or other company-specific practices which would support an inference of misrepresenting Best Prices. Therefore, the allegations fall woefully short under Rules 8(a) and 9(b).

Suffolk argues that it does not have access to Best Prices information because the data is uniquely within Defendants' control. See United States ex rel. Franklin v. Parke-Davis, 142 F. Supp. 2d 39 (D. Mass. 2001). While that may be true, Plaintiff still must allege sufficient facts regarding the circumstances of the fraudulent rebate scheme with respect to each Defendant. (See ¶¶ 81-93.) The fact that a manufacturer may have reported a fraudulent AWP, without more, will not suffice to plead a Best Prices fraud.

Suffolk has failed to make "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a). With the exception of Bayer Corporation, the



GSK Defendants, Abbott Laboratories, Inc., Pfizer Inc., TAP

Pharmaceutical Products, Inc., and Schering-Plough. Plaintiff

has failed to set forth at least minimal facts with respect to

(1) the allegedly fraudulent or false price reported to the state

for any specific drug; or (2) any information showing a company
wide scheme to misstate Best Prices. Educadores, 367 F.3d at 66
67. There are insufficient facts alleged to state a claim

showing entitlement to relief under any state causes of action.

#### D. Miscellaneous

The claims against Aventis Pharmaceuticals Inc. are dismissed for failure to plead a drug sold by Aventis Pharmaceuticals Inc., as opposed to Aventis Behring L.L.C.

The parties agree that Suffolk's AWP claims against Bayer for Cipro are not barred by the settlement agreements. Suffolk's Best Prices claims for Cipro from the time period from Third Quarter 1995 to Third Quarter 2000 are barred.

Suffolk's claims against Sanofi and Pharmacia are dismissed without prejudice to refiling to clarify the corporate structure and which Defendant is responsible for which drugs.

All claims against unnamed defendants, and all claims relating to unnamed drugs, are dismissed, as these fail to provide notice to the defendants.

#### ORDER



The Court ALLOWS (1) the motion to dismiss all claims against defendants Aventis Pharmaceutical Inc., Purdue Pharma, L.P., Novartis Pharmaceuticals Corporation, Ivax Corporation and Ivax Pharmaceuticals Inc., Sanofi-Synthelabo, Inc., and Pharmacia Corporation; and (2) the motion to dismiss the Best Prices claims against defendants Agouron Pharmaceuticals, Inc., Amgen, Inc., AstraZeneca Pharmaceuticals L.P., AstraZeneca US, Aventis Behring L.L.C., Barr Laboratories, Inc., Berlex Laboratories, Inc., Biogen, Inc., Bristol-Myers Squibb Company, Chiron Corporation, Eli Lilly and Company, Fujisawa Pharmaceutical Company, Ltd., Genentech, Inc., Immunex Corporation, Janssen Pharmaceutical, Johnson & Johnson, MedImmune, Inc., Merck & Co., Inc., Ortho Biotech, Ortho McNeil Pharmaceuticals, Reliant Pharmaceuticals, Warrick Pharmaceuticals, and Wyeth.

The Court **DENIES** the remainder of the motion.

S/PATTI B. SARIS

United States District Judge

# **EXHIBIT B**

## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	) MDL No. 1456 ) Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO: ALL ACTIONS	Judge Patti B. Saris Chief Magistrate Judge Marianne B. Bowler

### <u>DECLARATION OF JOHN P. MCDONALD IN SUPPORT OF SCHERING-PLOUGH'S</u> OPPOSITION TO COUNTY OF SUFFOLK'S SECOND MOTION TO COMPEL

John P. McDonald declares as follows:

- 1. I am a partner with the firm of Locke Liddell & Sapp LLP, and I represented Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation in *The State of Texas ex rel. Ven-A-Care of the Florida Keys, Inc. v. Warrick Pharmaceuticals, Schering-Plough Corp. et al.*, No. GV002327 in the 53rd Judicial District of Travis County, Texas (the "Texas Litigation"). I submit this declaration of my own personal knowledge in support of Schering-Plough's Opposition to County of Suffolk's Second Motion to Compel the Production of Discovery.
- 2. The claims for which the State of Texas and the relator sought recovery in the Texas Litigation related exclusively to Warrick Pharmaceuticals Corporation ("Warrick") and Warrick's products.
- 3. In response to discovery requests in the Texas Litigation, Schering-Plough Corporation, Schering Corporation, and Warrick made available for inspection over 150 boxes -- more than 400,000 pages -- of documents.

Case 1:01-cv-12257-PBS Document 1301-2 Filed 01/26/05 Page 11 of 12

4. It is my belief that the amount of documents produced in the Texas Litigation that do not relate exclusively to Warrick or Warrick products is minimal.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ John P. McDonald
John P. McDonald

Dated: January 24, 2005

### **CERTIFICATE OF SERVICE**

I hereby certify that on January 25, 2005, I caused a true and correct copy of the foregoing to be served on all counsel of record by electronic service pursuant to Case Management Order No. 2 entered by the Honorable Patti B. Saris in MDL 1456

/s/ Eric P. Christofferson

Eric P. Christofferson